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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/250,466 02/16/99 CHUDOKA

I RPE-27

EXAMINER

HM12/0703

JOHN B HARDAWAY III
HARDAWAY LAW FIRM
P O BOX 10107
FEDERAL STATION
GREENVILLE SC 29603-0107

LUNDGREN, J

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

07/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/250,466

Applicant(s)

CHUDOKA et al.

Examiner

Jeffrey S. Lundgren

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on 30 May 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 15, 16 and 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the kit is indistinguishable from the method. This is not found persuasive because the kit of Group II could be used for methods involving polymerase chain reaction or hybridization assays. The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Moreover, as to any question regarding the serious burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search between different groups, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-14, and 17-26, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims 2-14, and 17-26) are indefinite for reciting the term "changes", as one of skill in the art would not reasonably be able to determine how the biopolymers are changing (i.e., change is relative, a reference is required).

Claim 1 (and dependent claims 1-14, and 17-26) are indefinite for reciting the misspelled term "labelled". An amendment reciting "labeled" would overcome this rejection.

Claim 3 is indefinite for reciting the phrase "fixedly arranged" to describe how the biopolymers are presented. One of skill in the art would not reasonably be able to determine the metes and bounds of this limitation.

Claim 11 is indefinite for reciting the phrase "stem from" as one of skill in the art would not be able to determine the metes and bounds of this limitation.

Claim 20 is indefinite for reciting the term "sufficient" as a means to describe a number of probes, as one of skill in the art would not be able to determine how many probes would be sufficient and how many probes would not be sufficient.

Claim 21 is indefinite for reciting the term "interactively" as one of skill in the art would not be able to determine the metes and bounds of this limitation.

Claims 21 and 22, recite the limitation "the relative shifts" in a step of determination. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 is indefinite for reciting the phrase "positional correction" as one of skill in the art would not be able to determine the metes and bounds of this limitation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-14, 17-24, and 26, are rejected under 35 U.S.C. 102(e) as being anticipated by Garini et al (U.S. Patent No. 5,817,462, October 6, 1998).

Claims 1-14, 17-24, and 26, are drawn to method for identifying "changes" in biopolymers, utilizing different sets of labeled detector molecules, wherein the labeled detector molecules are DNA, and are fluorescently labeled. Furthermore, a localized calibrating probe may be used to calibrate for concentration and positional calibrations.

Garini et al. disclose a spectral imaging method for simultaneous detection of multiple fluorophores aimed at detecting and analyzing fluorescent in situ hybridizations employing numerous chromosome paints and/or loci specific probes each labeled with a different fluorophore or a combination of fluorophores for color karyotyping, and at multicolor chromosome banding, wherein each chromosome acquires a specifying banding pattern, which pattern is established using groups of chromosome fragments labeled with various fluorophore or combinations of fluorophores (see *Summary of the*

Invention; and Examples 6-8). Garini et al., account for the calibration of label intensities (column 24, line 66 to column 25, line 15) and positional calibrations, such as automatic calibrations (see Example 10).

Therefore, the claimed invention is anticipated by Garini et al.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garini et al., (U.S. Patent No. 5,817,462, October 6, 1998) in view of Kametsky et al. (U.S. Patent No. 5,107,422, April 21, 1992).

Claim 25 is drawn to the method of claim 23, wherein the calibrating probes are fluorescently-labeled particles.

Garini et al. disclose a spectral imaging method for simultaneous detection of multiple fluorophores aimed at detecting and analyzing fluorescent in situ hybridizations employing numerous chromosome paints and/or loci specific probes each labeled with a different fluorophore or a combination of fluorophores for color karyotyping, and at multicolor chromosome banding, wherein each chromosome acquires a specifying banding pattern, which pattern is established using groups of chromosome fragments labeled with various fluorophore or combinations of fluorophores (see *Summary of the Invention*; and Examples 6-8). Garini et al., account for the calibration of label intensities (column 24, line 66 to column 25, line 15) and positional calibrations, such as automatic calibrations (see Example 10).

Garini et al., do not disclose the use of fluorescently-labeled particles for calibrating imaged intensities.

Kamentsky et al., disclose an invention that features a method and apparatus for generating optical data that accurately estimates multiple constituents and simultaneously characterizes a number of morphological properties of each of a population of cells. The use of optical calibration particles, wherein the fluorescence intensities of the particles are used to in a calibration process is disclosed (see *Summary of the Invention*).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the calibration particles of Kamentsky et al. with the

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method of Garini et al., because the particles provide a means of intensity calibration (see M.P.E.P. 2144.07). Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

Conclusion

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren whose telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM (EST), and alternating Fridays from 8:00 AM to 4:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4028.

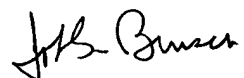
Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the Examiner of incoming facsimiles prior to sending papers to the aforementioned fax

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number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Jeffrey S. Lundgren, Ph.D.



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER